

WHAT IS CLAIMED IS:

1. An apparatus for evaluating a structure and function of a tissue-engineered construct under sterile conditions, said apparatus comprising:
  - (a) a base for supporting the tissue-engineered construct, said base including a housing having an inlet port and an outlet port;
  - (b) a main fluid circuit for allowing flow of a fluid media through said housing, said main fluid circuit having an efferent section in fluid communication with said outlet port and an afferent section in fluid communication with said inlet port;
  - (c) pressure means in fluid communication with said main fluid circuit for generating physiologic flow of the fluid media through said main fluid circuit;
  - (d) resistance means in fluid communication with said main fluid circuit for replicating an afterload characteristic, said resistance means positioned distal to the tissue-engineered construct on said efferent section of said main circuit; and
  - (e) control means in electronic communication with said pressure means for adjustably controlling the pressure of the fluid media in said main fluid circuit at a level which replicates intraluminal flow, wherein said intraluminal flow of said fluid through said main fluid circuit hemodynamically conditions the tissue-engineered construct prior to *in vivo* implantation in a ventricular outflow tract.
2. The apparatus according to claim 1, further comprising an auxiliary fluid circuit in fluid communication with said main fluid circuit to allow for regurgitant flow of said fluid media through said main fluid circuit.
3. The apparatus according to claim 2, wherein said auxiliary fluid circuit includes a check valve for allowing unidirectional flow through said auxiliary fluid circuit.
4. The apparatus according to claim 1, wherein said pressure means is a pump.

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5. The apparatus according to claim 4, wherein said pump is in fluid communication with said housing at a region upstream of said housing.
6. The apparatus according to claim 5, wherein said pump includes a check valve.
7. The apparatus according to claim 6, wherein said pump is a piston-driven pump.
8. The apparatus according to claim 6, wherein said pump is a bellows pump.
9. The apparatus according to claim 1, wherein said housing is hermetically sealed.
10. The apparatus according to claim 9, wherein said housing is composed of a transparent material.
11. The apparatus according to claim 10, wherein said transparent material comprises an acrylic polymer.
12. The apparatus according to claim 1, wherein said control means comprises a computer.
13. The apparatus according to claim 1, wherein said resistance means comprises an afterload device and a section of said efferent section comprises compliant tubing having elastic recoil.
14. The apparatus according to claim 1, wherein said afterload device generates pressure which substantially replicates aortic pressure.
15. The apparatus according to claim 1, further comprising a compressible container placed in fluid communication with said housing for allowing radial movement of the semilunar valve during the flow of said fluid media through said main fluid circuit.
16. The apparatus according to claim 14, wherein said container comprises a closed bag compliance reservoir.
17. An apparatus for evaluating a structure and function of a tissue-engineered construct under sterile conditions, said apparatus comprising:

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- (a) a base for supporting the tissue-engineered construct, said base including a housing having an inlet port and an outlet port;
- (b) a main fluid circuit for allowing flow of a fluid media through said housing, said main fluid circuit being in fluid communication with said inlet and outlet ports; and
- (c) pressure means in fluid communication with said main fluid circuit for generating physiologic flow of the fluid media through said main fluid circuit;

control means in electronic communication with said pressure means for adjustably controlling the pressure of said fluid media in said main fluid circuit.

- 18. The apparatus according to claim 17, further comprising an auxiliary fluid circuit in fluid communication with said main fluid circuit for allowing regurgitant flow of said fluid media through said main fluid circuit.
- 19. The apparatus according to claim 18, wherein said auxiliary fluid circuit includes a check valve for allowing unidirectional flow through said auxiliary fluid circuit.
- 20. The apparatus according to claim 17, wherein said pressure means comprises a pump.
- 21. The apparatus according to claim 20, wherein said pump is in fluid communication with said housing, said pump being positioned upstream of said housing.
- 22. The apparatus according to claim 21, wherein said pump includes a check valve for allowing unidirectional flow through said pump.
- 23. The apparatus according to claim 22, wherein said pump comprises a piston-driven pump.
- 24. The apparatus according to claim 22, wherein said pump comprises a bellows pump.
- 25. The apparatus according to claim 17, wherein said housing is hermetically sealed.

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26. The apparatus according to claim 25, wherein said housing comprises a transparent material.
27. The apparatus according to claim 26, wherein said transparent material comprises an acrylic polymer.
28. The apparatus according to claim 17, wherein said control means comprises a computer.
29. A method for evaluating the structure and function of a tissue-engineered construct under sterile conditions prior to *in vitro* implantation in a ventricular outflow tract, comprising the steps of:
  - (a) providing a hermetically sealed environment for supporting the tissue-engineered construct;
  - (b) providing a main fluid circuit for allowing flow of a fluid media through said hermetically sealed environment;
  - (c) generating physiologic flow of said fluid media through said main fluid circuit;
  - (d) replicating an afterload characteristic at an efferent section of said main circuit;
  - (e) controlling fluid flow through said main fluid circuit to a level which replicates intraluminal flow; and
  - (f) assessing valve function and intraluminal flow of said fluid media throughout a cardiac cycle.
30. The method according to claim 29, wherein said assessing step includes assessing at least one of effective orifice area, transvalvular pressure gradient, regurgitant flow area, leaflet dynamics, and leaflet energy expenditure throughout the cardiac cycle using ultrasonography.
31. The method according to claim 30, wherein said assessing step further comprises assessing at least one of forward and regurgitant flow patterns, volumes, and velocities using magnetic resonance imaging.

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